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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MUTUAL PHARMACEUTICAL COMPANY, INC., et al.,

Plaintiffs,

v.

WATSON PHARMACEUTICALS, INC., et al.,

Defendants.

Civil Action No.
09-5421(GEB)(TJB)

MEMORANDUM IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANT WEST-WARD PHARMACEUTICAL CORP.'S MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

In its premature and substantively deficient motion for summary judgment ("Motion"), West-Ward Pharmaceutical Corp. ("West-Ward") seeks to deprive Plaintiffs Mutual Pharmaceutical Company, Inc., AR Scientific, Inc., and AR Holding Company, Inc. (collectively "Mutual") of the right to prevent West-Ward's unlawful acts of unfair competition and false advertising on the sole ground that Mutual, years ago, distributed unapproved colchicine products manufactured by West-Ward and other parties. Mutual ceased all sales of unapproved drugs in July 2006 and promptly thereafter began efforts to obtain FDA approval for colchicine. West-Ward thus asks the Court to prohibit the one company that heeded the FDA's call to remove unapproved products from the market, and thereby improve patient safety, from pursuing Lanham Act claims against companies that ignored FDA pronouncements and continued reaping profits from sales of illegal, unapproved drugs.

Mutual should not be penalized for obeying the law, and West-Ward should not be rewarded for blatantly disregarding it. If the Court were to dismiss Mutual's claims based on unclean hands, the Court would create a disincentive for pharmaceutical companies to undergo the expensive and time-consuming FDA approval process, as pharmaceutical companies with unapproved products would still be able to market and advertise their unapproved products in a manner

designed to create consumer confusion, without consequences. This would directly contradict public policy created by the FDA and the principles of unfair competition law, and would be ultimately detrimental to the public health.

Putting aside the gross inequity and damage to public policy that would result from granting West-Ward's requested relief, West-Ward's Motion fails on purely legal grounds. Under well-established Third Circuit law, to prevail on its Motion West-Ward must prove by clear and convincing evidence that (a) there is a close nexus between Mutual's conduct – namely, distributing unapproved colchicine prior to July 2006 – and the actions of West-Ward that form the basis of Mutual's complaint (i.e., the continued sale, marketing and distribution of unapproved colchicine since July 2009, when Mutual obtained FDA approval for its COLCRYS® product); (b) Mutual's actions prior to July 2006 constituted "egregious misconduct" involving "fraud, unconscionability, or bad faith" directed at West-Ward; and (c) West-Ward was harmed by Mutual's purported unclean hands. West-Ward cannot satisfy any of those three requirements.

In comparing the conduct of the parties, West-Ward attempts to conflate two very different times by ignoring the different market and legal circumstances that existed prior to July 2006 and after July 2009. Mutual distributed unapproved 0.6 mg single-ingredient colchicine from 1993 to 2006 – a period of time in which there was *no FDA-approved colchicine product on the market*. In addition, the

significant scientific discoveries made by Mutual as a result of its efforts to obtain FDA approval for colchicine were unknown when Mutual distributed unapproved colchicine, and therefore Mutual's actions prior to July 2006 could not have contributed to any consumer confusion regarding the safety and efficacy of colchicine products.

In contrast, West-Ward has continued to market, advertise and sell unapproved colchicine since July of 2009, well after the FDA's much-publicized campaign to encourage drug manufacturers to seek FDA approval for all drug products; well after Mutual received FDA-approval for its COLCRYS® colchicine product; and well after Mutual discovered and publicized important safety information concerning the dosing regimen and potential health hazards associated with colchicine. Given the disparate circumstances surrounding the sale and distribution of pre- and post-FDA-approved colchicine, Mutual's conduct cannot be considered the same as West-Ward's.

West-Ward also cannot allege any facts to show that Mutual's conduct was directed at West-Ward or that West-Ward has suffered any injury from Mutual's sale of unapproved colchicine products from 1993 to 2006. The parties competed on equal footing in a time period where there was no FDA-approved product on the market. West-Ward could not have and did not suffer any injury at the hands of Mutual because there was no injury to suffer – the absence of any FDA-

approved colchicine necessarily meant there was no possibility of confusion regarding the FDA-approval status of West-Ward's colchicine as compared to anyone else's. Not one aspect of Mutual's conduct could be viewed as being directed at or injuring West-Ward. West-Ward's lack of injury is dispositive and its Motion should be dismissed on this ground alone.

For the reasons set forth above, West-Ward's Motion must fail based on the evidence adduced through the limited discovery conducted to date. That said, if the Court does not deny West-Ward's motion on substantive grounds, Mutual requests that the Court deny West-Ward's Motion on the ground that it is premature. West-Ward acknowledges that discovery is still ongoing. Document production by West-Ward and the other Defendants is incomplete and not a single deposition has been taken to date. Mutual's Rule 56(f) affidavit, filed herewith, identifies numerous facts upon which discovery could be conducted to refute the unclean hands theory espoused by West-Ward. Mutual therefore seeks an Order denying West-Ward's Motion with prejudice for both substantive and procedural reasons, or in the alternative, allowing a continuance to enable Mutual to undertake any and all other discovery necessary to obtain relevant facts.[1]

[1] Plaintiffs object to, and the Court should reject, West-Ward's reservation to file an additional summary judgment motion after discovery. *See* West-Ward's Memorandum in Support of Motion for Summary Judgment, p. 2, fn. 3. West-Ward's premature motion has unnecessarily wasted judicial and litigant resources, and West-Ward should not be rewarded with a second bite at the apple.

II. STATEMENT OF FACTS[2]

A. Mutual Ceased the Sale of Unapproved Drug Products in 2006.

In June 2006, the FDA publicly announced a new initiative to remove unapproved drugs from the marketplace, stating that:

> Manufacturers of drugs that lack required approval . . . have not provided FDA with evidence demonstrating that their products are safe and effective, and so we have an interest in taking steps to ***either encourage the manufacturers of these products to obtain the required evidence and comply with the approval provisions of the Federal Food, Drug, and Cosmetic Act (the Act) or remove the products from the market***.

SSDF at ¶2, *see also* Exhibit A to the Kottahachchi Decl. (emphasis added). Mutual adhered to the FDA's policy directive and implemented a plan to immediately pull out of the unapproved drug business.

Mutual took a significant step, strategically and financially, by halting the sale and distribution of unapproved colchicine. SSDF at ¶3. Mutual then acted to remove its unapproved colchicine product from the market by contacting the Price Lists and Wholesalers in July 2006 to inform them that Mutual had discontinued

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[2] The evidentiary support for the facts in Plaintiffs' Opposition is set forth in Plaintiffs' Supplemental Statement of Disputed Facts (referred to herein as "SSDF"), Responsive Statement of Material Facts ("RSMF"), the Declaration of G. Hayer ("Hayer Decl.") and the Declaration of N. Kottahachchi ("Kottahachchi Decl.") and exhibits thereto. In addition, the facts on which Plaintiffs need further discovery in order to oppose West-Ward's Motion are set forth in the Rule 56(f) Affidavit of B. Magrab.

the sale of all unapproved products, including unapproved single-ingredient 0.6mg colchicine. *Id*. at ¶6. Mutual went a step further by specifically requesting that all of its unapproved products, including unapproved colchicine, be removed from the Prices Lists and Wholesaler Ordering Systems. *Id.* Mutual also followed up with two Price Lists (Medi-Span and Redbook) in early 2009 to confirm that all of Mutual's unapproved products had been removed from their databases. *Id*.

Mutual has not shipped or sold a single unapproved drug, including unapproved single-ingredient 0.6 mg colchicine, since July 2006. *Id*. at ¶4. As a result of these good faith efforts to comply with the FDA's public policy goals, Mutual sacrificed millions of dollars in profits and incurred significant costs in terms of the time, money and resources needed to remove its product from the market. *Id* at. ¶7.

B. Mutual Becomes the Only Drug Manufacturer to Receive FDA Approval for Colchicine, Leading to the Discovery of Significant New Health and Safety Findings.

1. Mutual Obtains FDA Approval for Colchicine.

After Mutual ceased the sale of all unapproved drug products in 2006, it turned its efforts toward the time-consuming and costly process of obtaining FDA approval of its colchicine product. Mutual expended significant resources on the FDA review and approval process, which required a number of clinical trials, data assessment, and submissions to the FDA. SSDF at ¶7. In February 2007, Mutual

submitted an Investigational New Drug application ("IND") for colchicine. Hayer Decl. at ¶10. Mutual then filed a Request for Orphan Drug Designation in September 2007, and submitted a New Drug Application ("NDA") in June 2008, for 0.6 mg tablets containing colchicine as the sole active pharmaceutical ingredient for the treatment of Familial Mediterranean Fever ("FMF"). *Id.* at ¶12. In September 2008, Mutual filed a second NDA for 0.6 mg colchicine tablets, for the treatment of gout flares, and filed a third NDA in November 2008 for 0.6 mg colchicine tablets for the prophylaxis (prevention) of gout flares. *Id*. at ¶¶13-14.

After more than two years of working to satisfy the many requirements of the FDA and at a cost of tens of millions of dollars, in July 2009, Mutual obtained FDA approval to market and sell its COLCRYS® colchicine for the treatment of FMF. *Id*. at ¶15. This was followed by approvals to market and sell COLCRYS® for the treatment of gout flares later in July 2009 and for the prevention of gout flares in October 2009. *Id*. The FDA approvals entitled Mutual to a seven-year period to exclusively market COLCRYS for the treatment of FMF, and a three-year period to exclusively market COLCRYS for the treatment of gout flares. *Id*. at ¶16.

Despite the market exclusivity granted to Mutual by the FDA, West-Ward and the other defendants continue to market and sell their illegal and unapproved colchicine products in direct competition with Mutual. SSDF at ¶12; *see also* Complaint, generally.

2. Mutual's Efforts Result in Significant Health and Safety Findings About the Use of Colchicine.

In the process of approving Mutual's colchicine product, the FDA performed a comprehensive review of several clinical studies sponsored by Mutual that demonstrated the safety and efficacy of COLCRYS®. SSDF at ¶¶7-9. These clinical studies resulted in a number of significant new findings about the appropriate use of colchicine and the potential health hazards associated with the drug. Mutual's scientific advances and improvements in patient safety, which became public and were widely disseminated throughout the pharmaceutical community, included:

> (1) the development of new dosing regimens for COLCRYS® aimed at reducing the total amount of colchicine used by patients, which in turn significantly decreased the most common side effects from colchicine use (*i.e.*, adverse effects involving the gastrointestinal tract, including cramping, nausea, diarrhea, abdominal pain and vomiting) (*id.* at ¶8);
>
> (2) the discovery of potentially serious drug-drug and food interactions between colchicine and certain other foods and drugs, as well as specific dosing regimens that help ameliorate potential negative interactions (*id.*); and
>
> (3) the development of the more accurate and safer labeling of COLCRYS®, which now lists and warns of numerous drug-drug interactions, food interactions, contraindications, and the potentially dangerous accumulation of colchicine during chronic dosing (*id.*).

These findings and developments were not made until Mutual's successful efforts to obtain FDA approval for COLCRYS®, and the resulting information

obviously did not exist at the time Mutual distributed unapproved colchicine. *Id*. at ¶9. The FDA's approval also required Mutual to include a Medication Guide with COLCRYS®, which includes important warnings regarding various drug-drug interactions and food interactions. *Id*. at ¶10.

Despite the significance of these findings, West-Ward's product inserts and labels still fail to mention many of the drug-drug interactions, food interactions, and contraindications required by the FDA. *Id*. at ¶10-12. West-Ward also fails to provide its customers with a Medication Guide containing these important warnings.

C. West-Ward and Others Continue to Sell Unapproved Colchicine Products, Causing Consumer Confusion.

Mutual is the only drug manufacturer that has received FDA approval for a single-ingredient colchicine product. Contrary to the not-so-subtle suggestion in West-Ward's Motion that the FDA tacitly approves of West-Ward's sale of unapproved colchicine,[3] the FDA has in fact issued warning letters to at least three companies engaged in the manufacture and distribution of unapproved colchicine. SSDF at ¶14. In all three letters, the FDA clearly stated that colchicine requires FDA approval to be legally marketed in the United States. *Id*.

[3] For example, West-Ward seems to suggest that the inclusion of West-Ward's unapproved colchicine in the National Drug Code ("NDC") Directory somehow amounts to tacit approval or acquiescence by the FDA. *See* West-Ward Opening Brief at 3. However, the FDA makes perfectly clear that, "The inclusion of a firm or its products in the NDC Directory does not denote approval by the FDA of the firm or any of its marketed products." SSDF at ¶16.

Despite the FDA's approval of Mutual's COLCRYS® in July 2009, West-Ward continues to market, advertise, and sell its unapproved colchicine product through the Price Lists and Wholesalers. SSDF at ¶12. This is one of the critical differences between the conduct of Mutual and West-Ward. Prior to 2006, Mutual sold its unapproved colchicine along with other drug manufacturers at a time when (a) there was no FDA-approved single-ingredient colchicine product, and (b) the safety information resulting from Mutual's subsequent FDA approval efforts did not exist. SSDF at ¶13. West-Ward, on the other hand, continues to use distribution channels like Price Lists and Wholesaler Ordering Systems to sell its unapproved colchicine without FDA-mandated safety labeling and information, and with full knowledge that Mutual is the only company with FDA approval for a single-ingredient colchicine product. SSDF at ¶12.

West-Ward attempts to blur the distinction between the sale of unapproved colchicine prior to July 2006 (i.e., the Mutual conduct purportedly at issue) and the sale of unapproved colchicine from July 2009 to the present (i.e., the West-Ward conduct at issue) by including irrelevant and extraneous information in its argument – none of which bears upon the applicability of the unclean hands doctrine. Such efforts should not distract the Court from assessing the basic differences in the conduct of Mutual and West-Ward.

III. LEGAL STANDARDS

A. Summary Judgment

Summary judgment should be granted only if "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). An issue of material fact is genuine—and summary judgment must be denied—if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Restaurant Technologies, Inc. v. Allora*, 2008 WL 3843527, at *2 (D.N.J. Aug. 15, 2008).

As the party seeking summary judgment, West-Ward bears the initial burden of demonstrating the absence of any genuine issue of material fact. *Restaurant Tech.*, 2008 WL 3843527, at *2. It is then Mutual's burden to set forth specific facts showing that a genuine issue for trial exists. *Id*. In deciding West-Ward's Motion, the Court must view all the evidence presented in the light most favorable to Mutual. *Id*.

B. Unclean Hands

Courts may apply the equitable defense of unclean hands when "1) a party seeking affirmative relief 2) is guilty of conduct involving fraud, deceit, unconscionability, or bad faith 3) directly related to the matter in issue 4) that injures the other party 5) and effects the balance of equities between the litigants."

Castle v. Cohen, 676 F. Supp. 620, 627 (E.D. Pa. 1987). The defense is an "extreme sanction" and is narrowly applied. *Id*. (quoting *Pfizer, Inc. v. International Rectifier Corp.*, 538 F.2d 180, 195 (8th Cir. 1976)).[4] As a result, Mutual is presumed to have clean hands, and West-ward must prove the elements of the defense by "clear and convincing evidence." *Merisant Co. v. McNeil Nutritionals, LLC*, 515 F. Supp. 2d 509, 531 (E.D. Pa. 2007). While the unclean hands defense has been applied in Lanham Act cases, "such a defense is rarely successful due to 'a strong public interest in the prevention of misleading advertisements.'" *Bracco v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 465 (D.N.J. 2009) (quoting *Am. Home Prods. v. Johnson & Johnson*, 654 F. Supp. 568, 590 (S.D.N.Y. 1987)).

IV. ARGUMENT

A. Mutual's Marketing and Sale of Unapproved Colchicine Prior to July 2006 Does Not Constitute "Egregious Misconduct."

To successfully invoke the equitable defense of unclean hands, West-Ward "must introduce clear and convincing evidence of egregious misconduct." *Merisant*, 515 F. Supp. 2d at 531 (granting partial summary judgment for plaintiff and precluding defendant from raising unclean hands as a defense). That is, West-

[4] Despite West-Ward's claim that "Courts have consistently denied relief in false advertising cases on the basis of unclean hands," it fails to present a single Third Circuit case where a court granted summary judgment on the basis of the unclean hands defense in a false advertising case.

Ward must show that Mutual engaged in conduct "involv[ing] fraud, unconscionability, or bad faith *toward the moving-party*." *Jiffy Lube Int'l v. Jiffy Lube of Penn.*, 1992 WL 13682, at *11 (E.D. Pa. Jan. 27, 1992) (rejecting defendants' unclean hands argument in opposition to motion for preliminary injunction) (emphasis added); *see also Merisant*, 515 F. Supp. 2d at 531. West-Ward has not and cannot show that Mutual's conduct involved any degree of fraud, unconscionability, or bad faith, and certainly cannot demonstrate that any such conduct was directed at West-Ward.

West-Ward as the movant carries the heavy burden of providing clear and convincing evidence that no genuine dispute exists as to whether Mutual's conduct was "egregious." *Jiffy Lube*, 1992 WL 13682, at *11. In its attempt to establish this critical element, West-Ward relies entirely on the theory that Mutual's conduct was egregious because it sold unapproved colchicine product until July 2006, which purportedly caused confusion in the marketplace regarding the FDA-approval status of all colchicine products. *See* Defendant West-Ward Pharmaceutical Corp.'s Memorandum of Law In Support of Motion For Summary Judgment ("West-Ward Opening Brief") at 12 ("[T]o the extent that Defendants' conduct causes confusion in the marketplace … Plaintiffs' role in causing such confusion is indistinguishable."). This argument falls far short of proving that Mutual's conduct was egregious.

First, Mutual's conduct could not possibly have been fraudulent, unconscionable, or in bad faith when viewed in the context of the particular market circumstances, the FDA's policies, and the state of the relevant scientific research that existed prior to July 2006. The FDA did not launch its new drug safety initiative to remove unapproved drugs from the market until June 2006, at which point Mutual promptly ceased all sales of unapproved drugs. SSDF at ¶¶2-3. Thus, unlike West-Ward, Mutual never engaged in the marketing and sale of unapproved colchicine in the face of a clear mandate from the FDA that all drugs go through the FDA approval process.

Mutual's marketing and sale of unapproved colchicine also cannot be considered "egregious" given that there was *no FDA approved product* available at the time Mutual sold unapproved colchicine. *See* SSDF at ¶13. Prior to the launch of Mutual's FDA-approved COLCRYS® product, a relevant consumer could not have mistakenly confused an unapproved colchicine product for an FDA-approved colchicine product, or mistakenly believed that an unapproved colchicine product was legally substitutable for an FDA-approved colchicine product. The FDA's approval of COLCRYS® in July 2009 dramatically altered the landscape, however, and since then consumers have been and are likely to continue to be confused as to the FDA-approval status or substitutability of West-Ward's illegal colchicine vis-a-vis Mutual's safer, FDA-approved product.

In addition, Mutual's conduct was not fraudulent, unconscionable, or in bad faith because the marketing, sale, and distribution of unapproved colchicine by Mutual prior to July 2006 could not have caused consumer confusion about the *safety and efficacy* of its products because the discoveries of the new, safer dosing regimens, and potentially dangerous drug-drug and food interactions, were not made prior to 2007 (pursuant to the clinical studies that were conducted by Mutual during the FDA approval process between 2007 and 2009). SSDF at ¶¶8-9, 13. Mutual's marketing of its unapproved colchicine could hardly be characterized as egregious when the safety information available at the time was displayed on its product inserts and labels, and that same safety information was displayed on West-Ward's product inserts and labels. West-Ward Opening Brief at 12.

In short, Mutual did not market an unapproved drug with a dosing regimen *known to be outdated and potentially dangerous*, and it did not market an unapproved drug with *known and potentially fatal drug-drug and food interactions omitted*, as West-Ward continues to do today. SSDF at ¶¶8-9, 13. Because Mutual did not have the benefit of the clinical studies done during the FDA approval process that resulted in the development of new and important safety warnings, Mutual's conduct cannot be described as unconscionable, fraudulent, or in bad faith, and was certainly far from egregious.[5]

[5] Mutual's conduct is sufficiently distinguishable such that a finding that West-

Even assuming that creating consumer confusion, alone, amounted to the type of egregious conduct subject to an unclean hands defense, West-Ward has failed to present *any evidence* that Mutual's sales of unapproved colchicine caused any degree of consumer confusion. For example, West-Ward provides no consumer survey information, no expert witness data, no instances of actual customer confusion – in short, nothing. The principal reason that West-Ward has not provided any evidence regarding consumer confusion caused by Mutual's conduct prior to July 2006, let alone clear and convincing evidence, is because it is not possible for the reasons set forth above.[6]

Second, West-Ward has not presented any evidence that Mutual's conduct prior to July 2006 involved fraud, unconscionability, or bad faith *toward West-Ward. See Jiffy Lube*, 1992 WL 13682, at *11. Indeed, West-Ward essentially claims that up until July 2006, Mutual did exactly what West-Ward did to market

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Ward engaged in false advertising would not necessarily imply that Mutual had also engaged in false advertising. *See Merisant*, 515 F. Supp. 2d at 534-35 (distinguishing *Emco, Inc. v. Obst*, 2004 WL 137355 (C.D. Cal. May 7, 2004) and *Haagen-Dazs, Inc. v. Frusen Gladje Ltd.*, 493 F. Supp. 73 (S.D.N.Y. 1980), both cited by West-Ward, because, in those cases, "by definition, if the defendant were to be found liable … then the plaintiff should not be able to recover because its conduct was similarly inequitable").

[6] Significantly, even if West-Ward had put forth some purported evidence regarding consumer confusion, Plaintiffs, after the conclusion of fact discovery, would be able to counter such evidence with expert affidavits and/or expert deposition testimony. This is yet another example of the prematurity of West-Ward's motion.

and sell colchicine products, yet fails to point to a single fact suggesting that any of Mutual's behavior was directed toward West-Ward.

Because West-Ward has not shown by clear and convincing evidence that Mutual's conduct was "egregious" or directed at West-Ward, the Court should dismiss West-Ward's Motion. *See Zinn v. Seruga*, 2009 WL 3128353, at *24 (D.N.J. Sept. 28, 2009) ("Because the Court has not concluded that [defendant's] actions were fraudulent, unconscionable, or done in bad faith, the Court concludes that application of this doctrine is not appropriate."); *see also ACE Am. Ins. Co. v. Wachovia Ins. Agency, Inc.*, 2008 WL 4630486, at *10 (D.N.J. Oct. 17, 2008) ("This Court, therefore, holds that the instant context does not shock any moral sensibilities, and refuses to apply the doctrine of unclean hands in this matter."). Indeed, the only conduct that could properly be described as "involv[ing] fraud, unconscionability, or bad faith" has been West-Ward's blatant disregard of FDA guidance and public safety considerations. *Jiffy Lube*, 1992 WL 13682, at *11.

B. West-Ward Has Not Shown A "Very Close Nexus" Between Mutual's Purported Conduct And West-Ward's Actions As Alleged In Mutual's Complaint.

West-Ward must also prove by clear and convincing evidence that there is a "very close nexus" between West-Ward's conduct, as alleged in the complaint, and the alleged conduct by Mutual upon which West-Ward bases its unclean hands defense. *See Pharmacia Corp. v. GlaxoSmithKline Consumer Healthcare, L.P.*,

292 F. Supp. 2d 594, 610 (D.N.J. 2003); *see also Bracco*, 627 F. Supp. 2d at 465 n. 240 ("An unclean hands defense also requires that a plaintiff must have engaged in *precisely* the same behavior it accuses the defendant of conducting.") (emphasis added). West-Ward has made no such connection between Mutual's conduct and its own.

First, as discussed above, Mutual's past sale of unapproved colchicine is fundamentally different from West-Ward's current sales of unapproved colchicine because at the time Mutual sold unapproved colchicine, there was no FDA-approved product on the market and it was prior to the FDA's directive in June 2006. SSDF at ¶13. Furthermore, information about the proper dosing regimen and potentially dangerous drug-drug and food interactions had not yet been developed—breakthroughs that were made because Mutual stopped selling unapproved colchicine and devoted the time and resources necessary to obtain FDA approval for COLCRYS®. *Id*. at ¶¶8-9.

West-Ward, on the other hand, continues to market its unapproved colchicine despite the fact that (1) the FDA has publicly and repeatedly stated that such products require FDA approval, (SSDF at ¶2; *see also* RMSF at ¶38), (2) the FDA has warned at least three manufacturers of unapproved colchicine that their products were illegal because they were not approved by the FDA, (SSDF at ¶14), and (3) a legitimate FDA-approved colchicine product is now available on the

market (SSDF at ¶5). West-Ward persists in its illegal activities even though it knows that its product contains outdated and potentially dangerous dosing information and fails to warn about potentially harmful drug-drug and food interactions. SSDF at ¶¶10-12. West-Ward is willing to fly in the face of the FDA, and blatantly disregard public safety considerations, because it presumably continues to make tremendous profits from the sale of its unapproved product. SSDF at ¶15**.** For these reasons, it is clear that Mutual did not engage "in precisely the same behavior" as West-Ward. *See Bracco*, 627 F. Supp. 2d at 465 n. 240. Indeed, if West-Ward had engaged in precisely the same behavior that Mutual has (*i.e.*, had West-Ward stopped marketing and distributing unapproved colchicine and sought FDA approval), there would be no risk of consumer confusion, no threat to the public safety, and no need for this litigation.

Second, West-Ward argues that Mutual's hands are unclean because Mutual's unapproved colchicine allegedly still appears on one Price List - Medi-Span. Further discovery is necessary in order to allow Mutual to explore whether this fact is true. *See* Mutual's concurrently filed Rule 56(f) Affidavit. Nevertheless, even if this allegation were shown to be true, it would be insufficient to establish an unclean hands defense because Mutual stopped selling unapproved colchicine in July 2006. SSDF at ¶4. Mutual informed the Wholesalers and Price Lists, including Medi-Span, that it had discontinued the sale of all unapproved

products and requested that all such products, including unapproved single ingredient 0.6 mg colchicine, be removed from their databases. *Id*. at ¶¶3-4. Thus, years ago, Mutual took reasonable steps to remove its unapproved products from the pipeline. [redacted]

Even assuming that Mutual's unapproved (and expired) colchicine product appeared on a Price List as late as 2009, this fact does not prove that Mutual's conduct has a "very close nexus" to the conduct of West-Ward because, as alleged in the Complaint, West-Ward has not taken *any* steps to remove its unapproved products from the Price Lists and Wholesalers. SSDF at ¶12. West-Ward has presented no evidence that Mutual continues to place its unapproved colchicine tablets into commerce, nor does it allege that any sales of Mutual's unapproved colchicine products continue to occur. That certain distributors might continue to carry Mutual's expired product on their shelves, long after Mutual stopped manufacturing unapproved colchicine, sought FDA approval, and took steps to have the unapproved product removed from the market, bears no relevance to the conduct of Mutual at issue. West-Ward has failed to carry its burden to show that a sufficient nexus exists between Mutual's purported conduct and the conduct alleged by Mutual in its complaint. *See Pharmacia, L.P.*, 292 F. Supp. 2d at 610.

C. West-Ward Has Not Shown That It Was Injured As A Result Of Mutual's Conduct.

Under well-established law in this District and the Third Circuit, to establish a defense of unclean hands, West-Ward must show that it was injured as a result of Mutual's alleged misconduct. *See Zinn v. Seruga*, 2009 WL 3128353, at *24 (D.N.J. Sept. 28, 2009) ("The doctrine of unclean hands will deny equitable relief 'when the party seeking relief is guilty of fraud, unconscionable conduct, or bad faith directly related to the matter at issue that injures the other party and affects the balance of equitites.'") (quoting *Saudi Basic Indus. Corp. v. ExxonMobil Corp.*, 401 F. Supp. 2d 383, 386 (D.N.J. 2005)); *see also Merisant* 515 F. Supp. 2d at 531; *Pharmacia Corp.*, 292 F. Supp. 2d 594 at 610 ("[T]he defendant must do more than merely allege misconduct; there must also be a claim that the defendant was injured as a result of the misconduct.") (internal quotations omitted); *Jiffy Lube*, 1992 WL 13682, at *11 ("[D]efendants must show injury as a result of the misconduct and the misconduct must have a direct nexus with the right asserted by plaintiff."); *Castle* at 627 (refusing to apply unclean hands doctrine because the alleged conduct "did not injure defendants").

West-Ward has not alleged—let alone proved by clear and convincing evidence—that it was injured as a result of Mutual's conduct. Nor can it. In fact, West-Ward has actually benefitted from Mutual's conduct after June 2006 – specifically, Mutual's decision to obtain FDA approval for colchicine. As the

FDA has removed certain manufactures from selling unapproved colchicine (actions which were undoubtedly triggered by Mutual's efforts to gain FDA approval), [redacted] Each month that West-Ward manages to prolong this litigation equates to significantly more money in West-Ward's coffers, especially since West-Ward dramatically increased the price of its unapproved colchicine product after Mutual obtained FDA approval for COLCRYS®. SSDF at ¶17.

West-Ward's failure to even *allege* damage in an unclean hands defense is fatal to its Motion. For this additional reason, West-Ward's Motion should be denied.

D. The Public Interest Compels Denial Of West-Ward's Motion.

Courts have frequently noted that the unclean hands doctrine is equitable in nature, and, as a result, "cannot bar relief which is necessary and in the public interest." *See Alpo Petfoods, Inc. v. Ralston Purina Co.*, 720 F. Supp. 192, 194 (D. Col. 1989). Therefore, "when public health is at issue, as in false drug advertising, the unclean hands defense must be 'judiciously applied.'" *Bracco*, 627 F. Supp. 2d at 465 (quoting *McNeilab v. Am. Home. Prods. Corp.*, 501 F. Supp. 517, 539 (S.D.N.Y. 1980)).[7] Where the relief sought by the plaintiff "will accrue to the

[7] Tellingly, West-Ward does not cite a single case where summary judgment was granted on the basis of unclean hands in a false drug advertising case.

general benefit … a court may, and perhaps must, exercise its authority to see that what law and equity require is done." *McNeilab*, 501 F. Supp. At 539.

Here, Mutual seeks to stop West-Ward from (1) falsely representing that West-Ward's unapproved colchicine product is FDA-approved and/or substitutable for COLRCRYS®, when it is not, (2) falsely implying that West-Ward's unapproved colchicine is safer or more effective than COLCRYS®, when it is not, (3) providing consumers with a dosing regimen that has not been approved by the FDA and has been shown to increase the frequency of adverse effects, and (4) failing to warn consumers about potentially fatal drug-drug and food interactions. *See* Complaint generally. Putting an end to these false representations and dangerous marketing tactics serves the public interest because West-Ward's advertising could lead to consumers being unnecessarily harmed. The FDA has made quite clear its concerns about unapproved colchicine and has stressed the need for consumers to have accurate, approved information about the drug, as follows:

> The Agency has serious concerns that drugs marketed illegally without required FDA approval may not meet modern standards for safety, effectiveness, quality, and labeling, thereby posing a significant public health concern. The FDA drug approval process provides a review of product-specific information that is critical to ensuring the safety and efficacy of a finished drug product, and ensuring that health care professionals and patients have the information necessary to understand a

> drug product's risks and its safe and effective use. Although unapproved colchicine has been used for many years, FDA approved the first single-ingredient oral colchicine product, Colcrys, in July 2009 for the treatment of familial Mediterranean fever (FMF) and acute gout flares; in October 2009 Colcrys was approved for prophylaxis of gout flares (chronic gout). The approved prescribing information for Colcrys includes a new drug interaction warning, updated dosing recommendations and a medication guide. Pharmacists are reminded to dispense only FDA approved products.

See Exhibit O to Kottahachchi Decl. (attaching webpage from FDA website). The unclean hands doctrine therefore should not bar Mutual's claims, regardless of whether or not the Court determines that Mutual's hands are "unclean." *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 817, 851 (W.D. Tx. 2001) ("[I]f applying the doctrine would permit both parties to continue conduct detrimental to the public, the application of the doctrine will be rejected.").

Further, applying the unclean hands doctrine in this case would lead to an absurd result, and one that would eviscerate sound public policy. Mutual is the one party that heeded the FDA's edict, halted production of unapproved colchicine, devoted time and resources into obtaining FDA approval, and in the process discovered a more effective dosing regimen and potentially fatal drug-drug and food interactions. SSDF at ¶¶2-13. West-Ward, conversely, continues to illegally market its unapproved colchicine products despite Mutual's market exclusivity and

at least three FDA warning letters to other manufacturers, all at the risk of endangering the public safety. *Id*. at ¶¶12, 14.

If the Court dismisses Mutual's complaint based on unclean hands, the Court will (1) effectively create new public policy that is contrary to the FDA's initiative to encourage pharmaceutical companies to seek FDA approval of their drug products; (2) create a powerful disincentive for companies like Mutual to spend the time and resources to undergo the FDA approval process, since there would be no consequences for falsely advertising the FDA approval status, safety, and efficacy of a drug product; and (3) embolden parties like West-Ward to freeload off the efforts of parties like Mutual by continuing to deceptively market and sell unapproved products in a manner that flagrantly disregards the public health and is driven by a selfish desire to generate as much profit as possible without incurring any of the costs associated with FDA approval. The court of equity should not be used to facilitate such blatantly inequitable conduct.

E. The Cases Relied Upon by West-Ward Are Inapposite And Only Further Prove That Mutual's Conduct Does Not Warrant Application Of The Unclean Hands Doctrine.

The bulk of West-Ward's Motion consists of dubious allegations that are entirely irrelevant to an unclean hands assertion. In the few pages West-Ward devotes to actually addressing an unclean hands defense, it cites a handful of cases that are not from the Third Circuit, all of which are readily distinguishable from the

facts at hand.

The vast majority of the cases cited by West-Ward are simply inapposite because they involve situations where a court denied a plaintiff's motion for a preliminary injunction as a result of the potential presence of an unclean hands defense. West-Ward conveniently describes the results in these cases as instances in which courts "denied" or "barred relief" -- an obvious attempt to obscure that these cases do not involve motions for summary judgment and therefore do not support the present Motion. *See Stokely Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 534 (S.D.N.Y. 2009) (denying motion for preliminary injunction because potential unclean hands defense negated element of preliminary injunction); *Proctor & Gamble v. Ultreo*, 574 F. Supp. 2d 339, 356 (S.D.N.Y. 2008) (same); *Haagen-Dasz*, 493 F. Supp. 73, 76 (S.D.N.Y. 1980) (same); *Salomon Smith Barney, Inc. v. Vockel*, 137 F. Supp. 2d 599, 603 (same). The denial of a preliminary injunction is far less severe of a remedy than summary judgment, and does not require the court to conduct an in-depth analysis to assess whether a plaintiff's hands were unclean. Indeed, in all these cases, the court merely noted that the presence of a potential unclean hands defense defeated "likelihood of success on the merits" or "likelihood of irreparable harm." *See, e.g. Stokely Van Camp*, 646 F. Supp. 2d at 534; *Proctor & Gamble*, 574 F. Supp. 2d at 356.

The only two Lanham Act cases cited by West-Ward that actually dealt with a motion for summary judgment on the basis of unclean hands —both of which are from outside this Circuit and thus are not controlling—involve situations where the conduct alleged to be unclean was so substantially identical to the conduct complained about by the plaintiff that a finding that defendant had committed false advertising necessarily implied a finding that plaintiff's hands were unclean. *See Rainbow Play Sys., Inc. v. Backyard Adventure, Inc.*, 2009 WL 3150984, at *6 (D.S.D. Sept. 28, 2009) ("If Defendants have engaged in inequitable conduct by referring to a tree that is not classified as cedar in a scientific botanical classification, Rainbow has also engaged in inequitable conduct."); *Stokely Van Camp*, 646 F. Supp. 2d at 533 (noting that the parties made "virtually identical" claims); *Proctor & Gamble*, 574 F. Supp. 2d at 355 (same); *Emco*, 2004 WL 137355 at *5 (applying unclean hands doctrine where the court found that both parties made false statements of fact about the country of origin of their goods); *but see Merisant*, 515 F. Supp. 2d at 534-35 (distinguishing *Emco* and refusing to apply the unclean hands doctrine because in *Emco* the conduct alleged to be unclean and the conduct alleged in the complaint were so substantially identical that "by definition, if the defendant were to be found liable [at trial]… then the plaintiff should not be able to recover because its conduct was similarly inequitable.").

The cases relied upon by West-Ward actually demonstrate that the unclean hands doctrine is inapplicable here because Mutual's conduct was not "substantially identical" or "precisely the same" as West-Ward's conduct. Mutual never marketed an unapproved colchicine product at a time when a FDA-approved product was on the market, never marketed a colchicine product that included a dosing regimen known to increase the incidence of adverse effects, and never marketed a colchicine product that failed to warn about known potentially fatal drug-drug and food interactions. West-Ward did and continues to do so. Here, the Court could (and should) conclude that West-Ward engaged in false advertising without also finding that Mutual did as well. Summary judgment, therefore, is improper.

F. Unclean Hands Does Not Apply to Plaintiffs' Damages Claims.

Even if the Court were to find that West-Ward met its burden of proving unclean hands by clear and convincing evidence and granted West-Ward's Motion, this case must still proceed to trial on the issue of Mutual's damages because unclean hands is an equitable defense that cannot bar Mutual's remedies at law. *See Miller v. Beneficial Mgmt. Corp.*, 855 F. Supp. 691, 717 (D.N.J. 1994) ("[The] doctrine of unclean hands operates to deny a suitor the special remedies of equity, leaving him his remedies at law.") (internal quotations omitted); *Gen. Dev. Corp. v. Binstein*, 743 F. Supp. 1115, 1133-34 (D.N.J. 1990) (holding that the unclean

hands defense "is only applicable with respect to the plaintiff's claim for equitable relief . . . ."); *Inter Med. Supplies Ltd. v. EBI Med. Sys., Inc.*, 975 F. Supp. 681, 687 (D.N.J. 1997) ("Since defendants' motion seeks relief from the jury's verdict, and not from any award of injunctive relief, the 'unclean hands' doctrine is not applicable."). Thus, West-Ward's Motion seeks relief (complete termination of this action) that cannot be granted and should therefore be denied.

V. CONCLUSION

For the foregoing reasons, Mutual respectfully requests that the Court deny West-Ward's Motion with prejudice.

Respectfully submitted,

Dated: August 23, 2010

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